Dear Prescriber,

This letter contains critically important information regarding compliance with the Medicaid Tamper Resistant Requirements.

- As of October 1, all fee-for-service Medicaid prescriptions that are either handwritten or printed from an EMR / ePrescribing application must contain at least one feature from each of the three categories of tamper resistance (see below for details). Note compliance as of April 1, 2008 only required one feature from one category of tamper resistance so continuing in compliance for October may require additional steps by your prescription pad or software vendor.
- Prior guidance for printed prescriptions generated from EMRs or ePrescribing applications stated that special copy resistant paper would likely be required for printed prescriptions to be in compliance as of October 1, 2008. CMS has clarified this statement, and is now stating that while special paper may be used to achieve copy resistance it is not necessary. EMR or ePrescribing generated prescriptions may be printed on plain paper, and be fully compliant with all three categories of tamper resistance provided they contain at least one feature from each of the three categories detailed below.

As of October 1, 2008, all handwritten and/or computer generated (by electronic medical records or ePrescribing applications) printed prescriptions for fee-for-service Medicaid patients, must be fully compliant with federal and/or state guidance for prescription tamper resistance. While the first phase of tamper resistance guidance required prescribers to use at least one feature from one category of tamper resistance, this second phase requires that these handwritten or computer printed Medicaid prescriptions contain at least one industry recognized feature from each of the three categories of tamper resistance. Prescriptions for Medicaid patients that are telephoned, faxed, or ePrescribed are exempt from these tamper resistance requirements.

As the October 1 implementation date approaches, we want to provide you with the information you need to ensure Medicaid patients will be able to receive their needed medications and ensure that the transition to these new prescription requirements is as smooth as possible for recipients, pharmacists, physicians, and other prescribers. We hope this guidance will help you comply with the requirements.

While these requirements are federally mandated, individual states are responsible for issuing guidance which may be more (but not less) proscriptive than the guidance below. Some states have already issued guidance which is pertinent for this second implementation phase, and others have not. Many states have and are likely to continue accepting and forwarding to the prescriber community, the National Council for Prescription Drug Programs (NCPDP) guidance below. It is likely that the company who supplies your prescription pads/paper, and/or Electronic Medical Records (EMRs) / ePrescribing software is aware of these additional requirements and will be able to work with you to ensure your Medicaid prescriptions comply with the requirements in your state.

For additional information on your specific state requirements, it is suggested that you either check your state Medicaid Web site or the National Association of State Medicaid Directors Web site at www.NASMD.org/issues/TRPP.asp.

#### Review of CMS Requirements for October 1, 2008

By October 1, 2008, a handwritten or computer generated and printed prescription must contain at least one feature in **all three** categories. No feature may be used twice:

- 1) One or more industry recognized features designed to prevent unauthorized copying of a completed or blank prescription.
- 2) One or more industry recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.
- 3) One or more industry recognized features designed to prevent the use of counterfeit prescriptions.

The following best practices are strongly suggested for adoption to meet the tamper-resistant requirements (See Appendix I for examples):

#### **Best Practices for Tamper Resistant Printed Prescriptions**

|   | Feature  | Description  |
|---|--|--|
| Category 1:<br>Copy Resistance                | A) Void/Illegal/Copy Pantograph with or without Reverse Rx B) Micro print signature line for prescriptions generated by an EMR if they cannot produce Void/Illegal/Copy Pantograph with or without Reverse Rx              | The word "Void," "Illegal," or "Copy" appears when the prescription is photocopied.  Very small font which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied.  |
| Category 2: Erasure / Modification Resistance | A) An Erasure revealing background (resists erasures and alterations) for written prescriptions or printed on "toner-lock" paper for laser printed prescriptions, and on plain bond paper for inkjet printed prescriptions | Background that consists of a solid color or consistent pattern that has been printed onto the paper. This will inhibit a forger from physically erasing written or printed information on a prescription form.  Toner-lock paper is special printer paper that establishes a strong bond between laser-printed text and paper, making erasure obvious. Note—this is NOT necessary for inkjet printers—as the ink from inkjet printers is absorbed into normal "bond" paper. |
|   | B) Quantity check off boxes, refill indicator (circle number of refills or "NR"), or border characteristics (dispense and refill # bordered by asterisks and optionally spelled out) for prescriptions generated by an EMR | In addition to the written quantity on the prescription, quantities are indicated in ranges.  Quantities and refill # are surrounded by special characters such as an asterisks to prevent modification, e.g. QTY **50**.  |
| Category 3: Counterfeit Resistance            | A) Security features and descriptions listed on the prescription   | A Complete list of the security features on the prescription paper aids pharmacists in identification of features and determine compliance   |

CMS has determined that states which had tamper-resistant prescription pad programs, with the exception of Idaho, in place prior to the passage of the law are all in compliance with the October 1 deadline. For your reference, a copy of the standards for each of the following states is attached as Appendix II.

California Maine
Florida New Jersey
Idaho<sup>1</sup> New York
Indiana Texas
Kentucky Wyoming

#### **Note for prescription pad users**

If your current prescription pad vendor cannot meet the needs of the requirements, the following Web sites list vendors that comply with the requirements of states that already mandate tamper-resistant prescription pads for some or all prescriptions. The vendors listed below can meet or exceed all three CMS requirements:

California: <a href="http://www.ag.ca.gov/bne/security\_printer\_list.php">http://www.ag.ca.gov/bne/security\_printer\_list.php</a>

Florida: <a href="http://floridamedicaid.consultec-">http://floridamedicaid.consultec-</a>

inc.com/XJContent/RX\_07\_071003\_Prescription\_Pad\_List\_ver1.2.xls?id=000005500053

Indiana: http://www.in.gov/pla/3207.htm

**Maine**: <a href="http://www.mainecarepdl.org/index.pl/home/tamper-resistant-prescription-pads">http://www.mainecarepdl.org/index.pl/home/tamper-resistant-prescription-pads</a>

On average it should take 2 to 4 weeks for your new prescriptions pads/paper to arrive once you have placed your order with a prescription pad vendor. If you are using a new prescription pad vendor for the first time, keep in mind that your shipment may take longer since the vendor will need to process your information.

Appendix III summarizes features, including and in addition to the best practices above, that could be used on a tamper-resistant pad/paper in compliance with the CMS guidelines to meet the requirements for October 1. They are categorized according to the three types of tamper-proof features described by CMS.

#### **Suggested Actions**

I. Make sure that your prescription pads or printed prescriptions contain at least one industry-recognized feature in each of the three categories listed above. Best practice examples of prescription pads and computer generated prescriptions that meet all three categories are described above and shown below.

II. Contact your prescription pad vendor to secure an appropriate supply of tamper-resistant prescription pads and/or paper that will meet your state's requirements on October 1, 2008; or contact your EMR / ePrescribing vendor to make sure that your use of the application to print prescriptions will be compliant by October 1, 2008.

<sup>&</sup>lt;sup>1</sup> Because it only requires a feature to prevent copying, Idaho's current program complies only with the first stage of the implementation process.

#### **Impact on Medicaid Patients**

In order to ensure that patients do not see any adverse impact regarding their access to medications, it is critical for you to meet **all three** CMS requirements, prior to October 1. In an emergency situation, prescriptions written on non-tamper resistant pads will be permitted as long as the prescriber provides a verbal, faxed, electronic, or compliant written prescription within 72 hours after the date on which the prescription was filled.

Thank you for your efforts to comply with these new requirements.

Yours Truly,

#### Appendix 1

#### **Best Practices for Tamper Resistant Printed Prescriptions (Handwritten)**

#### Category 1

A) Photocopied "COPY", "ILLEGAL", or "VOID" Pantograph

#### Category 2

- A) An Erasure revealing background (resists erasures and alterations)
- B) Quantity check off boxes
- C) Refill indicator (circle number of refills or "NR")

#### Category 3

A) Security features and descriptions listed on the prescription

# **Appendix 1 (continued)**

## **Front**

Void or Copy Pantograph: displays "VOID" or "ILLEGAL" on a color copy of an Rx. It will appear on a wide range of copier settings. (Cat. 1)

|  | HELEN<br>Lic: 123456 | 5678<br>C. DOE, M.D.<br>• DEA: XX1234567<br>2222222222 |
|--|----------------------|--|
| PATIENT'S FULL NAME  | SE                   | DATE OF BIRTH  |
| ADDRESS  |                      | DATE   |
| Preprinted Text Fields: Concern the check boxes, refill indicated preprinted limitations or gumake the Rx harder to mo (Cat.2) | rs, and idelines     | 00000000000000000000000000000000000000                 |
|  |                      |  |
|  | PRESCRIBER'S SIG     | NATURE   |

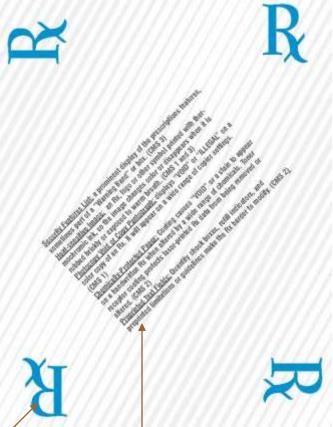
Thermochromic ink, so the image changes color or disappears when

Heat-sensitive Image: An Rx, logo, or other symbol printed with

it is rubbed briskly or exposed to warm breath. (Cat. 1 and 3)

# Back

Chemically-Protected Paper: Invisible coating causes "VOID" or a stain to appear on a handwritten Rx when altered by a wide range of chemicals. Toner receptor coating protects laser-printed Rx data from being removed or altered. (Cat. 2) Recommended for use with Preprinted Text Fields



Security Features List: a prominent display of the prescriptions features, sometimes part of a "Warning Band" or box. (Cat. 3)

Example of a Color **Copied Prescription** 

| DAYTON  | CHMYTER DRIVE<br>CHI 45/408<br>4 * FAX 1-937 434-962 | 10   |
|---|--|--|
| JOHN R. SMITH, M.D.<br>Lic. 123456 + DEA. 3X1234567<br>1415 222222222 | Lic (2565) +   | DOE, M.D.<br>DEA XX1254567<br>ZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZ             |
| PASTENT B PULL HAME.  | 8EX  | DATE OF BIRTH  |
| ADDRESS   | n n s  | DATE   |
| R.  |  | 0000000<br>0.1-24<br>0.25-49<br>0.074<br>0.75-100<br>0.101-100<br>151 and over |
| Talan a sana ta   | RESCRIPTS SOAT                                       |  |
| <sub>ISST</sub> Refile 1 2 3 4<br>IREA No Refile Void After           | DEA #  | ROLLED EUBSTANCS   |

Hollow Pantograph: VOID or ILLEGAL is designed to not obscure or block vital information. Often showing strongest intensity at the "top" or the document. These pantographs generally do not "pop" on a black and white fax

#### Appendix I (continued)

#### **Best Practices for Tamper Resistant Printed Prescriptions (Generated by an EMR)**

#### Category 1

A) Copy Resistance: Microprint signature line\*

#### Category 2

- A) Modification / Erasure Resistance: Border characteristics (dispense and refill # bordered by asterisks AND spelled out)
- B) Modification / Erasure Resistance: Printed on "toner-lock" paper for laser printed prescriptions, and on plain bond paper for inkjet printed prescriptions

#### Category 3

A) Counterfeit Resistance: Listing of security features

 $*Microprint\ Line\ viewed\ at\ 5x\ magnification$  this is an original prescription-this is an ori

#### Example A

| Washington Medical Group 555 Pennsylvania Ave, Washington DC 2 202-222-2222 (Fax) 202-222-1111  Name Jane Q Public Addr 123 Main Street City Washington, DC 20001 | 20001           | <b>Date</b> 06/29/2008<br><b>DOB</b> 07/04/1960<br><b>Ph:</b> 202-555-5555 |
|---|-----------------|--|
| HYDROCHLOROTHIAZIDE 12.5 MG (<br>morning<br>Generic: HYDROCHLOROTHIAZIDE<br>Disp ***30*** THIRTY (2)<br>Refill ***3*** THREE                                      | CAPS One (1) ta | ab by mouth each   |
| Security Meatures: (*) bound & spelled quantities, microp<br>must show THIS IS AN ORIGINAL PRESCRIPTION' &  |                 |  |

Category #1 – Copy Resistance: Microprint signature line\*

Category #2 – Modification / Erasure Resistance: Border characteristics (dispense and refill # bordered by asterisks AND spelled out)

Category #2 – Modification / Erasure Resistance: Printed on "toner-lock" paper for laser printed prescriptions, and on plain bond paper for inkjet printed prescriptions

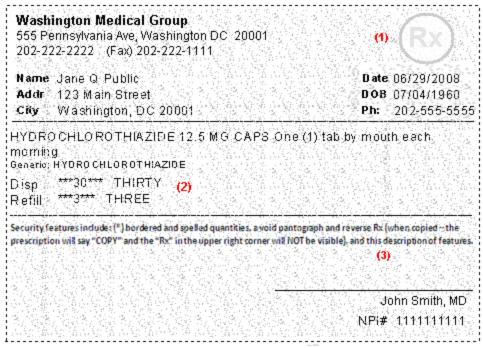
Category #3 – Counterfeit Resistance: Listing of security features

THIS IS AN ORIGINAL PRESCRIPTION-THIS IS AN ORIGINAL PRESCRIPTION-THIS IS AN ORIGINAL PRESCRIPTION-THIS IS AN ORIGINAL PRESCRIPTION

<sup>\*</sup>Microprint Line viewed at 5x magnification

#### **Appendix I (continued)**

### Example B



Category #1 – Void/Illegal/Copy Pantograph with or without Reverse Rx

Category #2 – Modification / Erasure Resistance: Border characteristics (dispense and refill # bordered by asterisks AND spelled out)

Category #2 – Modification / Erasure Resistance: Printed on "toner-lock" paper for laser printed prescriptions, and on plain bond paper for inkjet printed prescriptions

Category #3 – Counterfeit Resistance: Listing of security features

## **Appendix II**

# Tamper-Resistant Prescription Pad Security Features Required by States Prior to April 1, 2008

| State              | Security Features  |
|--------------------|--|
| California         | Prescription pads must be printed from approved vendors only.  |
|                    | "Void" pantograph, security prescription watermark, chemical void protection, area of opaque         |
|                    | writing, quantity check boxes with units, printed on security paper, security back printing, listing |
|                    | of security features, thermo chromatic ink, batch numbering, separate vendor ID, sequential          |
|                    | numbering starting at 0001 at each new order. <sup>1</sup>   |
| Florida            | Prescription pads must be printed from approved vendors only.  |
|                    | "Void" or "Illegal" pantograph (green or blue), erasure safe paper, background ink that resists      |
|                    | reproduction, watermarked paper, security feature listing (face or back), batch number which         |
|                    | includes vendor ID, physicians license verification required by vendor.                              |
| Idaho <sup>2</sup> | Non-copyable paper ONLY <sup>1</sup>   |
| Indiana            | "Void" pantograph (blue), Security Back print, quantity check boxes, refill quantity and "void"      |
|                    | after" wording, one prescription per form, dispense as written/may substitute wording.               |
| Kentucky           | "Void" pantograph (green), Security Back print, quantity check boxes, refill quantity and "void      |
|                    | after" wording, one prescription per form, dispense as written/may substitute wording. 1             |
| Maine              | "Void" pantograph, repetitive watermark on backside, thermo chromatic ink, list of security          |
|                    | features. <sup>1</sup>   |
| New Jersey         | Prescription pads must be printed from approved vendors only.  |
|                    | State seal on face and back for pantograph, "Rx" graphic on face, blue face with black imprint,      |
|                    | green back, batch number which includes vendor ID, 8 standard formats, pre-printed batch             |
|                    | number, physicians license verification required by vendor, shipment log by vendor, prescription     |
|                    | blanks for each prescriber or health care facility must be numbered consecutively.                   |
| New York           | "Void" pantograph, thermo chromatic ink, diagonal lines, micro fine printing, serial number and      |
|                    | bar code.  |
| Texas              | "Void' pantograph, thermo chromatic ink, erasure safety paper, security features listed, control     |
|                    | number.  |
| West Virginia      | "Void" pantograph (green), Security Back print, quantity check boxes, refill quantity and "void      |
|                    | after" wording, one prescription per form, dispense as written/may substitute wording.               |
| Wyoming            | Prescription pads must be printed from approved vendors only. 1                                      |
|                    | "Void" Pantograph, erasure protection on a colored background, security features listed,             |
|                    | physician license verification by vendor. <sup>1</sup>   |

For controlled substances only.
 Because it only requires features to prevent copying, Idaho's current program complies only with the first stage of the implementation process.

# **Appendix III**

# Summary of features that could be used on a tamper-resistant pad/paper in compliance with the CMS guidelines

Category 1 – Copy Resistance: One or more industry recognized features designed to prevent unauthorized copying of a completed or blank prescription form.

| Feature  | Description  |
|--|--|
| "Void," "Illegal," or "Copy" pantograph with or without Reverse "Rx"   | The word "Void," "Illegal," or "Copy" appears when the prescription is photocopied. Except where state law mandates the word "Void" or "Illegal" – it is recommended that the pantograph show the word "Copy" if the prescription is copied. The pantograph should be configured so as not to obscure the security feature description contained on the prescription, the patient and prescriber demographics, or the medication and directions.  Some pantographs can be problematic because when the prescription is copied, the resulting "void" or other wording that appears makes the underlying prescription difficult to read. This type of pantograph should be avoided. We suggest that you ask your pad vendor about hollow "VOID" pantograph lettering which is less likely to obscure the prescription information. |
|  | The Reverse Rx disappears when copied at a light setting – thus making the pantograph more effective in copy resistance. The pantograph may be used with a reverse Rx, but Reverse Rx is not effective as a feature by itself.   |
| Micro printing – To be effective, this feature must be printed in 0.5 font or less making it illegible to the pharmacist when copied | Very small font which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied.   |
| Thermochromic ink  | Ink changes color with temperature change.   |
| Coin-reactive ink  | Ink changes color when rubbed by a coin.   |
| Watermarking Security back print (artificial watermark)  | Printed on the back of prescription form. The most popular wording for the security back print is "Security Prescription" or the security back print can include the states name. Can only be seen when viewed at an angle.  |
| Digital watermarks   | Weak digital watermarks cannot be read if copied and strong digital watermarks provide digital rights management/"proof" of origin when copied.  |
| Watermarking on special paper  | Special paper contains a watermark that can be seen when backlit.  |

# **Appendix III (continued)**

|   | : One or more industry-recognized features designed                                     |
|---|---|
| to prevent the erasure or modification of informati | on written / printed on the prescription by the   |
| prescriber.   |   |
| Features to Prevent Erasure                         | Description   |
| An erasure revealing background (erasure            | Background that consists of a solid color or  |
| resistance)   | consistent pattern that has been printed onto the                                       |
|   | paper. This will inhibit a forger from physically                                       |
|   | erasing written or printed information on a   |
|   | prescription form. If someone tries to erase, the                                       |
|   | consistent background color will look altered and                                       |
|   | show the color of the underlying paper.   |
| Toner Receptor Coating / Toner Lock or Color        | Special printer paper that establishes a strong bond                                    |
| Lock paper (erasure resistance for computer         | between laser-printed text and paper, making  |
| generated prescriptions <u>printed with a laser</u> | erasure obvious. Note – this is NOT necessary for                                       |
| <u>printer</u> )                                    | inkjet printers – as the ink from inkjet printers is absorbed into normal "bond" paper. |
| OR  | absorbed into normal bond paper.  |
| OK  |   |
| Chemically reactive paper (erasure resistance for   | If exposed to chemical solvents, oxidants, acids, or                                    |
| hand written prescriptions)                         | alkalis that can be used to alter the prescription, the                                 |
|   | chemically reactive paper will react and leave a  |
|   | mark visible to the pharmacist.   |
| Features to Prevent Modification                    | Description   |
| Quantity check off boxes and refill indicator       | In addition to the written quantity on the  |
| (circle or check number of refills or "NR)          | prescription, quantities are indicated in ranges. It is                                 |
|   | recommended that ranges be 25's with the highest  |
|   | being "151 and over". The range box   |
|   | corresponding to the quantity prescribed MUST be  |
|   | checked for the prescription to be valid.   |
|   | The refill indicator indicates the number of refills                                    |
|   | on the prescription. Refill numbers must be used to                                     |
|   | be a valid prescription.  |
| Pre-printed language on prescription paper          | Reduces ability to add medications to the   |
| I brossiphon baker                                  | prescription. Line must be completed for this   |
| Example: "Rx is void if more than XXX Rx's on       | feature to be valid. Computer printer paper can   |
| paper"  | accommodate this feature by printing, "This space                                       |
|   | intentionally left blank" in an empty space or  |
|   | quadrant.   |
| Quantity and Refill Border and Fill (this is the    | Quantities and refill # are surrounded by special                                       |
| recommended for computer generated                  | characters such as an asterisks to prevent  |
| prescriptions)                                      | modification, e.g. QTY **50** Value may also be   |
|   | expressed as text, e.g. (FIFTY), (optional).  |

Please note that while ONLY one feature from this Category 2 is required, it is strongly recommended that one feature of erasure resistance and one feature of modification resistance be

used. Inkjet printed prescriptions are de-facto erasure resistant based on the characteristics of inkjet ink.

# **Appendix III (continued)**

| Category 3 – Counterfeit Resistance: One or   | more industry-recognized feature designed to prevent   |
|---|--|
| the use of counterfeit prescription forms.  |  |
| Feature   | Description  |
| Security features and descriptions listed on prescriptions – this feature is <u>strongly</u> recommended on all prescriptions | Complete list of the security features on the prescription paper for compliance purposes. This is strongly recommended to aid pharmacists in identification of features implemented on prescription.   |
| Thermochromic ink   | Ink changes color with temperature change.   |
| State Approved Vendor ID  | This feature is only effective in states with an approved vendor listing.  |
| Serial number   | Number issued by printer of prescription or uniquely assigned by EMR or ePrescribing software; may or may not be sequential. Only valid if reported and tied to the pharmacy claim adjudication process. NY is the only state that has this system currently in place. |
| Encoding techniques (bar codes)   | Bar codes on prescription. Serial number or Batch number is encoded in a bar code.   |
| Security Thread   | Metal or plastic security threads embedded in paper as used in currency.   |